IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA	**:**	**CRIMINAL NO. 21-**
v.	**:**	**DATE FILED: 4/5/21**
MURTY VEPURI	**:**	**VIOLATION: 21 U.S.C. §§ 331(d), 355(a), and 333(a)(1)**
	:	**(delivery into interstate commerce of unapproved drugs)**

INFORMATION

COUNT ONE

THE UNITED STATES ATTORNEY CHARGES THAT:

At all times material to this information:

1. KVK-TECH, INC. ("KVK") was a generic drug manufacturer headquartered in Newtown, PA. KVK manufactured and distributed drugs under its own label to national wholesalers and major retail chains. Among other prescription drugs, KVK manufactured and distributed Hydroxyzine Hydrochloride ("Hydroxyzine") tablets indicated for anxiety, tension, and allergic reactions. The active pharmaceutical ingredient ("API") in Hydroxyzine tablets was hydroxyzine hydrochloride ("Hydroxyzine HCl"). API produced a drug's intended effect and had a significant impact on drug safety and efficacy.

2. Defendant MURTY VEPURI caused the ownership of KVK to be placed in three equal shares in private trusts for the benefit of defendant VEPURI's three children.

3. Defendant MURTY VEPURI directed day-to-day operations and made key business decisions for KVK, including decisions related to drug regulatory requirements, drug composition, drug manufacturing quality, purity, and potency, and the purchase of API to manufacture drugs, including the purchase of Hydroxyzine HCl for the manufacture of Hydroxyzine tablets. Defendant VEPURI used the title "advisor" or "consultant" when interacting with persons outside of KVK, including government personnel, although all KVK officers and employees were subject to his direction and control.

THE FOOD AND DRUG ADMINISTRATION

4. The United States Food and Drug Administration ("FDA") was the federal agency responsible for protecting the health and safety of the public by enforcing the Federal Food, Drug, and Cosmetic Act ("the Act ") and ensuring, among other things, that drugs intended for use in humans were safe and effective for their intended uses. Pursuant to this responsibility, the FDA promulgated and enforced regulations relating to the approval, manufacture, and distribution of drugs.

5. The Act defined drugs as, among other things, articles intended for use in the diagnosis, cure, mitigation, treatment, and prevention of disease in man, and articles (other than food) intended to affect the structure of any function of the body of man. 21 U.S.C. § 32l(g)(l)(B) and (C).

6. A "new drug" was defined as any drug "the composition of which is such that the drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for

use under the conditions prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. §321(p)(1).

6. The Act prohibited introducing or delivering for introduction, or causing the introduction or delivery for introduction, into interstate commerce any new drug without an approved New Drug Application ("NDA") or any generic drug without an approved Abbreviated New Drug Application ("ANDA"). 21 U.S.C. §§ 331(d) and 355(a).

7. Among other disclosures, the FDA required that every NDA/ANDA contain information regarding the intended uses of the drug; specifications related to the drug components, processes and controls used during manufacture of the drug itself; specifications related to containers and closure systems, packaging materials and methods; and the product labeling, including exterior labeling and package inserts. The FDA's determination about the safety and efficacy of a drug, which was the basis for approval, was based on the drug and drug components, including the API, being manufactured at specified facilities, in a specific strength and dosage form, and packaged, held, and labeled in a specific manner. Thus, an "approved" new drug was the pill, tablet, or liquid, all aspects of which matched the description of the drug in the FDA-approved NDA/ANDA, including that the drug was produced at the FDA-registered manufacturing facility identified in the NDA/ANDA. If a drug differed in a condition established in an approved NDA/ANDA, it was not the approved drug, and the FDA could not ensure that the drug was safe and effective for its intended use.

HYDROXYZINE

8. On or about March 2007, the FDA approved ANDA 40-786; ANDA 40-787; and ANDA 40-788 (collectively "the ANDAs") that allowed KVK to legally market Hydroxyzine 10 mg. tablets, 25 mg. tablets; and 50 mg. tablets, respectively. According to the ANDAs, the drug would be produced with Hydroxyzine HCl manufactured by UCB Pharma, S.A. ("UCB") at its facility in Braine-l'Alleud, Belgium. In or about December 2008, FDA approved KVK's supplemental application to produce Hydroxyzine tablets with Hydroxyzine HCl manufactured by Cosma, S.p.A at its facility in Ciserano, Italy.

9. On or about October 29, 2010, at the direction of defendant MURTY VEPURI, KVK purchased a non-returnable, commercial quantity of API, that is, Hydroxyzine HCl, manufactured by Dr. Reddy's Laboratories ("DRL") in Moreles, Mexico, for the purpose of manufacturing and distributing Hydroxyzine 50 mg. tablets, 25 mg. tablets, and 10 mg. tablets. UCB, which no longer manufactured the API in Belgium, offered the API manufactured in Mexico through a contract relationship with DRL. KVK's approved ANDAs did not include DRL in Mexico as an API manufacturer.

10. On or about January 4, 2011, KVK obtained the first of three shipments of API manufactured by DRL in Mexico. KVK used the unapproved API to manufacture Hydroxyzine. KVK failed to notify the FDA that it was using API manufactured by DRL in Mexico to manufacture Hydroxyzine, contrary to the FDA regulatory requirements.

11. On or about April 12, 2011, KVK began distributing Hydroxyzine 50 mg. tablets, that contained API manufactured by DRL in Mexico, to its customers that were

national wholesalers and large retail pharmacies. The Hydroxyzine tablets as manufactured did not conform with the approved ANDA on file with the FDA.

12. On or about May 6, 2011, KVK began distributing Hydroxyzine 25 mg. tablets, that contained API manufactured by DRL in Mexico, to its customers that were national wholesalers and large retail pharmacies. The Hydroxyzine tablets as manufactured did not conform with the approved ANDA on file with the FDA.

13. On or about June 5, 2011, the FDA issued a Warning Letter after it identified significant violations of current Good Manufacturing Practices ("cGMP") at the DRL facility in Mexico during an inspection on or about November 8, 2010 through on or about November 11, 2010. As a result of the cGMP deficiencies, the FDA concluded that API manufactured at DRL in Mexico was adulterated. The FDA was unaware that KVK had been importing API manufactured by DRL in Mexico through UCB. On or about July 7, 2011, FDA issued an import alert for API manufactured by DRL in Mexico to protect the American public from potentially adulterated drugs. The import alert banned the import into the United States of API manufactured by DRL in Mexico, and it remained in effect until on or about July 12, 2012.

14. After the FDA issued the Warning Letter and import alert, KVK continued to sell the unapproved Hydroxyzine 50 mg., 25 mg., and 10 mg. tablets containing API manufactured by DRL in Mexico. From in or around July 2011 through in or around October 2013, KVK caused the distribution of at least approximately 368,311 bottles of unapproved Hydroxyzine tablets to patients throughout the United States. The Hydroxyzine tablets did not conform with the approved ANDA on file with the FDA.

15. In or about May 2013, KVK placed an order for another commercial production quantity of API manufactured by DRL in Mexico. On or about June 3, 2013, United States Customs intercepted and refused entry into the United States of 19 drums of DRL Hydroxyzine HCl destined for KVK on the grounds the API was an unapproved drug substance.

16. The FDA inspected KVK's facilities from on or about November 14, 2013 through on or about December 9, 2013 ("the inspection"). During the inspection, FDA discovered that KVK had distributed Hydroxyzine tablets that contained API manufactured by DRL in Mexico, for which the FDA had not received notice and there was not an approved ANDA on file with the FDA.

17. From in or about April 2011 through in or about October 2013, including on or about October 21, 2013, in the Eastern District of Pennsylvania, and elsewhere, defendant

MURTY VEPURI

caused to be introduced and delivered into interstate commerce Hydroxyzine tablets that were new drugs within the meaning of 21 U.S.C. § 321(p), that were not approved by the FDA under 21 U.S.C.§ 355(a).

All in violation of 21 U.S.C. §§ 331(d) and 333 (a)(1).

Ronald Gavach for

JENNIFER ARBITTIER WILLIAMS
ACTING UNITED STATES ATTORNEY

*No.*_ _ _ _ _ _ _ _ _ _

UNITED STATES DISTRICT COURT

Eastern District of Pennsylvania

Criminal Division

THE UNITED STATES OF AMERICA

vs.

MURTY VEPURI

INFORMATION

21 U.S.C. §§ 331(d), 355(a), and 333(a)(1) (delivery into interstate commerce of unapproved drugs – 1 count)

A true bill.

_____
Foreman

Filed in open court this _____day,
Of _____A.D. 20_____

_____
Clerk

Bail, $_____